

Notified Body
Identification number

0805



Australian Government

Department of Health
Therapeutic Goods Administration

Certificate Number
MRA Q00090

EC Certificate

Full Quality Assurance Procedures

Annex II, excluding section 4, of the Council Directive 93/42/EEC on Medical Devices

Issued to

Manufacturer Name: Taylor Surgical Instruments Pty Ltd
Manufacturer Address: Unit 7 / 1498 Ferntree Gully Road
KNOXFIELD VIC 3180
Australia

For the Design and Manufacture of device categories listed on page 2 of this certificate.

This is to certify that the Full Quality Assurance System described below conforms to the relevant provisions of Annex II, excluding section 4, of the Council Directive 93/42/EEC on medical devices. Certification is based on an examination of the Full Quality Assurance System which applies at every stage from design to final controls.

This certificate has effect at all times from the commencement date, until the end of the period specified in the certificate (expiry date), or unless it has been suspended or revoked.

Commencement Date: 20 September 2019
Certificate Expiry Date: 26 May 2024
Associated CA Certificate: AU Q00232

This certificate is issued by:

Dr Ying Huang
Signed electronically
Delegate of the Secretary
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia

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Scope of Certificate

Manufacturer Facilities

Name and Address		Scope
1	Taylor Surgical Instruments Pty Ltd Unit 7 1498 Ferntree Gully Road Knoxfield VIC 3180 Australia	Design and manufacture of electrosurgical electrodes

Design and Manufacture of Device Categories

Description		Limitations (if applicable)
1	Electrosurgical electrodes	

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Certificate History

Version	Details	Issue Date	File Reference
1.1	Initial certification	31 August 2015	2014/048912
1.2	Minor editorial changes to the certificate	27 July 2016	2014/048912
2.1	Recertification	20 September 2019	E19-527131
Certificate Location (Manufacturer Root File Number):			2010/010758